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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,160	07/09/2001	Jack V. Smith		7063

7590  
JACK V. SMITH  
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07/27/2004

EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/901,160	SMITH, JACK V.	
	Examiner	Art Unit	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/31/2003 has been entered.

### *Amendments*

Applicants' amendments to the drawings and the specification are not in a proper format. Information on how to effect drawing changes is given below. Amendments to the specification should include a marked-up copy of the entire paragraph being amended.

### *Specification*

The following grammatical errors appear in the specification. Applicants are requested to review the specification in its entirety to assure that no other errors or misspellings are present.

- At page 2, line 14, the phrase "art device" should be inserted after the term "prior".
- At page 2, line 15, the second occurrence of the term "to" should be deleted.
- At page 5, line 21, the term "have" should be "having".
- At page 10, line 17, the second occurrence of the term "has" should be deleted.
- At page 11, line 24, "To further explain the" is in incomplete sentence.

### *Drawings*

Applicants have not submitted corrected drawings in the proper format. Applicants should note the following information on how to effect drawing changes and submit the proper drawing changes.

### **INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

#### **Replacement Drawing Sheets**

Drawing changes must be made by presenting replacement figures which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments, or remarks, section of the amendment. Any replacement drawing sheet must be identified in the top margin as "Replacement Sheet" and include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin.

#### **Annotated Drawing Sheets**

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be submitted or required by the examiner. The annotated drawing sheets must be clearly labeled as "Annotated Marked-up Drawings" and accompany the replacement sheets.

#### **Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability.

*Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Guirguis et al.

Guirguis et al teach a device for both collecting and testing a fluid specimen, in particular urine. With respect to claim 1, the device comprises a specimen container (15) having a collection chamber (40) for collecting a fluid specimen and an opening (25) allowing fluid to be placed into the container. The device also includes a cap (20) for sealing the container. A test chamber (80) having a test agent (95) is equivalent to Applicants' claimed assay means (col. 5, line 60 – col. 6, line 3). The test agent (95) is preferably a test strip such as an immunochromatographic test strip (col. 6, lines 3-6). At col. 6, lines 63-67, Guirguis et al teach that the device may include test strips for detecting drugs of abuse or for performing multiple tests for multiple analytes. At col. 7, lines 1-6, Guirguis et al teach that at least two test strips, preferably five or six test strips may be present in the device to test for different analytes. Figures 1-3 show the test chamber being position on an outside wall of the device, as recited in claim 3. Further with respect to claim 1, Guirguis et al teach activating the assay means by penetrating a frangible bottom wall (75) of the isolation chamber (65) with a fluid releasing element (100) which is preferably in the form of a spike (102), which is equivalent to

Applicant's claimed shaft means (col. 7, lines 14-24). Guirguis et al further teach the use of a shaft and shaft chamber (176) at col. 13, lines 43-61 and figures 18-22. With respect to claim 2, Guirguis et al teach that fluid communication between the isolation chamber and the test chamber holding the test strips is facilitated by a fluid flow path (32). This fluid flow path is equivalent to Applicant's claimed lateral flow means. With respect to the method of claim 4, Guirguis et al teach, collecting a sample into the collection chamber (40) of the device, sealing the device with the lid (20), which activates the fluid releasing element (100) causing fluid to flow via the fluid flow path (32) into the test chamber (80), where the fluid contacts reagents on the test strips to analyze the constituents of the fluid. See col. 8, lines 12-42.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(e) in view of the teachings of Guirguis et al.

### ***Response to Arguments***

3. Applicant's arguments filed 12/31/03 have been fully considered but they are not persuasive. Applicants have several concerns with the anticipatory rejection over Guirguis et al. First, Applicants argue that the Guirguis et al reference teaches the use of a spike, and equates the spike to a plunger. Since the claims recite "without the use of a plunger, tilting or plenum", Applicants argue that the reference cannot anticipate the claims. In response, the Examiner does not view a plunger as equivalent to a spike, which would make the Guirguis et al reference non-anticipatory. In fact, at col. 7, lines 7-24, Guirguis et al teaches that the spike (102) is a penetrating portion for piercing the frangible wall (75) and allowing the fluid specimen to move into contact with the assay in the test chamber. Guirguis et al further teach that instead of using a spike, a plunger or plug may be used. Penetrating means, such the spike

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taught by Guirguis et al, are not excluded by the claims. Rather, the Examiner has interpreted the spike of Guirguis et al to be equivalent to the shaft that Applicants describe in their own specification at page 10. ("Once the shaft has been depressed (activated) the inner wall of the chamber has becomes [sic] perforated and fluid enters the shaft chamber..."). Similarly, Guirguis et al teach perforating an inner wall using the spike (102).

Secondly, Applicants argue that the Examiner used hindsight. In response, the Examiner would like to note that hindsight goes to "obviousness". Since, no obviousness rejection has been made, there can be no "hindsight reconstruction of the invention". Likewise, the rejection is not "pieced together" since only one reference has been used.

Next, Applicants attempt to distinguish the lid of Guirguis et al from that of the instant invention by stating that the lid of Guirguis activates the device and is required for activation, whereas the lid of the instant invention does not. In response, it should be noted that the instant claims recite "cap means for sealing the container means opening". In this respect, the lid of Guirguis et al is indeed equivalent to that of Applicants in that it seals the collection cup. The fact that the lid of Guirguis also activates the device is not relevant in this instance for two reasons: Firstly the claims do not exclude the lid operating to activate the device and secondly, the operation of the lid involves its functions. In claims directed to an apparatus, per se, the function of the components is insufficient to impart allowability to the claims because device claims are limited by their components, and not their function. See MPEP 2114.

Applicants have requested constructive assistance from the Examiner. In response to this Office Action, the Examiner requests that Applicants provide a full explanation of how the instant device operates so the Examiner can help Applicants determine some claim language that may overcome the anticipatory rejection. Specifically, the Examiner is interested in the

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activation means, the shaft and the shaft chamber. It is not readily clear from the specification at page 10-11 how these components actually work. So, to better assist Applicants, the Examiner will need further explanations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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